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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,484	03/26/2004	Palpu Pushpangadan	11378.59USW1	8114
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MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			EXAMINER LEITH, PATRICIA A	
			ART UNIT 1655	PAPER NUMBER
			MAIL DATE 11/15/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/810,484	Applicant(s) PUSHPANGADAN ET AL.	
	Examiner Patricia Leith	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/27/07.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,7-9 and 84-87 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,7-9 and 84-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/10/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1, 3-5, 7-9 and 84-87 are pending in the application and were examined on their merits.

Applicant's arguments pertaining to the previous rejections are persuasive due to the most recent amendments to the claims on 8/27/07.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-5, 7-9, 84 and 86-87 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 has been amended to recite 'alcohol extract.' It cannot be found in the original disclosure where 100% alcohol was used for extraction. Rather, the

Art Unit: 1655

Specification teaches that diluted alcohol was used; that is, a mixture of alcohol and water. Applicant is required to either delete the New Matter in the claims or to point out specifically where the original Disclosure contains this information in order to overcome this rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

Art Unit: 1655

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-5, 7-9 and 85-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al. (2002) in view of Abdul Hamid et al. (2002).

Chang et al. (2002) taught the advantageous use of natural antioxidants to foodstuffs in order to extend the shelf-life of food (to retard oxidation) (see Introduction, p. 347). Chang et al. investigated the antioxidant activity of the ethanolic, methanolic and acetone extracts of sesame coat (the seed coat of *Sesamum indicum* L. (white)) and verified that the sesame coat extracts had strong antioxidant activity equal to Vitamin E (see entire reference, especially p. 348, 'Materials and methods', p. 349 2.12 'Test of antioxidant activity', Table 1 and Figures 1 and 2). It is noted that at least the experiment of 2.4 'Antioxidant activity in a linoleic acid system' on p. 348 was carried out with 20% of the sesame coat extract (i.e., .2 ml : 1ml).

Chang et al. did not specifically teach the incorporation of an alcohol extract of *Centella asiatica*, the specific percentages of *C. asiatica* or wherein the ethanol was aqueous ethanol.

Abdul Hamid et al. (2002) reported that *Centella asiatica* L. was long-known to countries such as Sri Lanka, Madagascar, South Africa and Malaysia as a medicine as well as a food (see Introduction, p. 465). Abdul Hamid et al. demonstrated the antioxidant properties of ethanolic extracts from *Centella asiatica* leaves, roots and petioles via the conjugated diene method (see entire reference, especially p. 466-468).

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for having antioxidant activities. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients as established by *In re Kerkhoven* (*supra*) as well as , *In re Sussman*, 136 F.2d 715, 718, 58 USPQ 262, 264 (CCPA 1943). Accordingly, the instant claims, in the range of percentages where no

Art Unit: 1655

unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal percentages of extracts because the alcoholic extracts from *Sesamum indicum* as well as *Centella asiatica* were both art-recognized result-effective variables which would have been routinely determined and optimized in the pharmaceutical art. Additionally, the percentages as Instantly claimed are rather meaningless in that no particular active ingredient is known or stated in any specific concentration. Rather, the extracts are given as a percentage in a total composition. The efficacy of the plant extracts will be based upon the concentration of active components in that extract and not based upon the percentage of the extract in the composition *per se*. For example, a composition comprising 1% of an alcoholic extract of sesame may contain a *very small* amount of active ingredient because the extract, containing endogenous plant chemicals *and solvent*, may contain a large amount of solvent, thus diluting the active ingredients. On the other hand, 1% of an alcoholic extract of sesame may be concentrated; that is, that the solvent has been removed in-part or completely, thus yielding an extract with a higher percentage of active ingredients. Further, the amount of the active ingredient in 1% of extract will also depend upon the extent to which the plant matter is extracted. If

a plant is extracted for only one minute, the extract will likely contain a small, or even trace amount of active components derived from the plant material. On the other hand, an extraction which occurs for 24 hours will contain a much larger amount of active ingredient. The differences between Applicant's claimed method and that suggested by the combined teaching of the prior art, appear minor in nature. Although the prior art does not teach all the various percentages of components, it would be conventional and within the skill of the art to identify the optional percentages of extracts in a composition in order to treat patients of varying ages and weights, or alternatively, to optimize storage of foods which possess varying degrees of oxidation.

Although neither reference specifically taught wherein alcohol/water was used as the solvent, it is deemed that claim 85 is broad enough to read on a trace amount of water present in alcohol. This is obvious over the prior art in that a trace amount of water added to alcohol as the solvent would not have made a difference in the extracted materials of sesame or *Centella asiatica*. It is deemed that absent evidence thereof, that the extracts of sesame and *Centella asiatica* whether extracted in ethanol or an ethanol/water mixture would be the same, or so similar that no discernable differences could be made. "As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' composition differs and, if so,

Art Unit: 1655

to what extent, from that of discussed references. Therefore, with the showing of the references, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Further, it is clear from both references, that the extracts were diluted in a diluent prior to antioxidant testing. Therefore, 'syrup', 'suspension', 'diluent' and 'elixir' are all made obvious by the combination of references. Also, it is deemed that each of the extracts was suitable for oral administration in that 1) Chang et al. specifically suggested the use of the ethanolic extract of sesame seed coat as an antioxidant for the food industry (see 'Results and discussion' pp. 349-350) and 2) Abdul Hamid et al. specifically taught that the extracts of *Centella asiatica* were well-known to be taken internally (again, see the Introduction, p. 465).

Claims 1, 3-5, 7-9 and 84-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al. (2002) in view of Abdul Hamid et al. (2002) in view of Hjorth (US 2001/0046990 A1).

The teachings of Chang et al. (2002) in view of Abdul Hamid et al. (2002) were discussed *supra*. Chang et al. and Abdul Hamid et al. did not specifically teach a diluent such as microcrystalline cellulose.

Art Unit: 1655

Hjorth (US 2001/0046990 A1) taught that antioxidants as well as plant extracts were routinely tableted with known diluents such as microcrystalline cellulose (see claims 1-17).

One of ordinary skill in the art would have been motivated to combine a diluent such as microcrystalline cellulose with sesame seed coat ethanolic extract and *Centella asiatica* ethanolic extract in order to provide an easily administered oral dosage tablet.

Again, it was already known in the art that the ethanolic extracts of sesame seed coat and *Centella asiatica* (leaves, inter alia) were antioxidants. It is deemed that formulation of known, medicinal compositions into known, medicinal formulations such as tablets with known tableting excipients such as microcrystalline cellulose would have been obvious to the ordinary artisan at the time the invention was made.

The Supreme court has acknowledged that:

When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. **If a person of ordinary skill can implement a predictable variation..103 likely bars its patentability...**if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill. A court must ask whether the improvement is more than the predictable use of prior-art elements according to their established functions...

... the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results (see *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 U.S. 2007) emphasis added.

Art Unit: 1655

[If]... there are [a] finite number of identified, predictable solutions, [a] person of ordinary skill in art has good reason to pursue known options within his or her technical grasp, and if this leads to anticipated success, it is likely product of ordinary skill and common sense, not innovation *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 U.S. 2007. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 1655

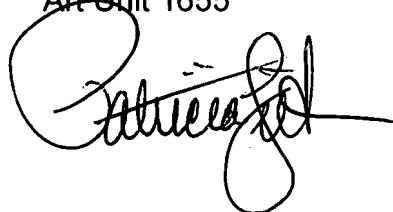
extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655



November 2, 2007